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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,829	01/13/2006	David W. Old	(17710)AP	3665

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EXAMINER	
GALLIS, DAVID E	
ART UNIT	PAPER NUMBER
1609	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,829	OLD ET AL.	
	Examiner	Art Unit	
	David E. Gallis	1609	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1 and 5* is/are allowed.

6)☒ Claim(s) *2-4 and 6-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1 through 10 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 9, related to a method comprising administering an effective amount of a claimed prostaglandin analog to a mammal in treatment of glaucoma or intraocular hypertension, is rejected under 35 U.S.C. 112, first paragraph as based on a disclosure which is not enabling. Study results that are critical or essential to the practice of the invention, but not included in the claim is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). Experimental results that would enable determination of an effective amount of the claimed prostaglandin analog are referred to in the specification but not included in the specification. Page 23, lines 5 and 6 refers to compounds of Table 1 which may be tested for biological activity, even though no such table is present in any part the instant application. Likewise, page 25, lines 7 through 10 recites "The results of the activity studies presented in the table will demonstrate that the compounds disclosed herein are have activity characteristic of prostaglandins and are thus useful for the treatment of glaucoma, ocular hypertension, and other diseases or conditions related to prostaglandin activity." No such tabulation of results needed to demonstrate the therapeutic effectiveness or relative activities of

the claimed prostaglandin analogs is available within the specification, or any other part of the instant application.

4. Claim 9 is also are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of glaucoma and intraocular hypertension, does not reasonably provide enablement for preventing those conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with this claim. Applicants are not enabled for "preventing" those conditions. The only established prophylactics are vaccines not the prostaglandin analog compounds such as present here. In addition, it is presumed that "prevention" of the claimed conditions would require a method of identifying those individuals who will develop the claimed conditions before they exhibit symptoms. There is no evidence of record that would guide the skilled clinician to identify those who have the potential of becoming afflicted.

"The factors to be considered [in making an enablement rejection] have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in that art, the predictability or unpredictability of the art, and the breadth of the claims", In re Rainer, 146 USPQ 218 (1965); In re Colianni, 195 USPQ 150, Ex parte Formal, 230 USPQ 546. 1) As discussed above, preventing those conditions requires identifying those patients who will acquire the condition before the symptoms occur. This would require extensive and potentially opened ended clinical research on healthy subjects. 2) Glaucoma and

intraocular hypertension are the conditions Applicant intends to treat. 3) There is no working example of such a preventive procedure in man or animal in the specification. 4) The claim rejected is drawn to ophthalmologic medicine and is therefore physiological in nature. 5) The state of the art is that no general procedure is art-recognized for determining which patients generally will become afflicted before the fact. 6) The artisan using Applicants invention would be a Board Certified physician in ophthalmologic diseases with an MD degree and several years of experience. Despite intensive efforts, pharmaceutical science has been unable to find a way of getting a compound to be effective for the prevention of diseases generally. Under such circumstances, it is proper for the PTO to require evidence that such an unprecedented feat has actually been accomplished, In re Ferens, 163 USPQ 609. No such evidence has been presented in this case. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, Genentech vs. Novo Nordisk, 42 USPQ2nd 1001, 1006. This establishes that it is not reasonable to any agent to be able to prevent these conditions generally. That is, the skill is so low that no compound effective generally against these disorders has ever been found that can prevent such conditions. 7) It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved", and physiological activity is generally considered to be an unpredictable factor. See In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). 8) The claim broadly reads on all patients, not just those undergoing therapy for the claimed conditions and on the multitude of compounds embraced by the prostaglandin analog of claim 9.

The Examiner suggests deletion of the words “or preventing”.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2, 3, 4, 6, 7, 8, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 3, 4, 7, and 8 recite the limitation "the compound of claim 1..." (either claim 1 directly or serially through intervening dependent claims). There is no antecedent basis for this limitation in the claim. The illustrated compound in each of these dependent claims features an unsubstituted terminal phenyl group on the ω chain. This presupposes an optional hydrogen as a claim 1 defined R group. Clearly no such R group option is available in claim 1.

Claims 6 and 10 recite the limitation "the compound having an ω chain comprising..." followed by a drawn structure of an entire prostaglandin molecule. While the structure in claim 6 contains an ω chain, the entire structure can not be the ω chain. Also, the said “alteration(s)” of the structure recited in claims 6 and 10, item (a.) encompass “adding, removing, or substituting a non-hydrogen atom of the ω chain”. This alteration is far too ambiguous to interpret, since substituting atoms in the ω chain structure can potentially eliminate the chain or eliminate significant substituents and carry into a completely different class of compounds. Additional claim 6 and 10 ambiguity is found in “alteration(s)” of the structure recited in claims 6 and 10, item (b.) where there alteration of the carboxyl group (CO2H) is specified. While the structure

presented in claims 6 and 10 has a carboxyl group, the ω chain of the structure does not. Throughout these claims, there is no clarity regarding whether the ω chain or the entire prostaglandin structure is the object of alteration.

This rejection can be overcome by grammatically clarifying whether the ω chain or the prostaglandin structure is the subject of the claim with the illustration specifically showing the ω chain group or the prostaglandin structure. Furthermore, adding, removing, or substituting a non-hydrogen atom of the ω chain will require clearly defined addition, elimination and substitution positions within the chain and the optional atoms or groups which will ultimately define disclosed and enabled prostaglandin species. Also, reference to the CO2H group conversion will need to be eliminated from the claim if the ω group is the subject of the claim.

Allowable Subject Matter

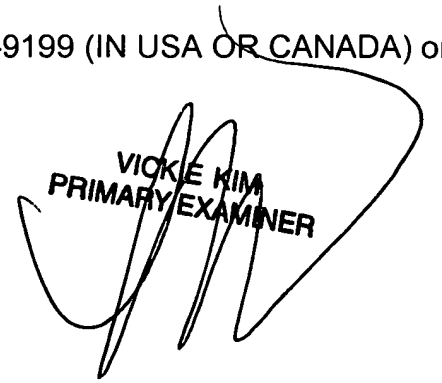
7. Claims 1 and 5, relevant to prostaglandin analog compounds constitute allowable subject matter for the following reasons. The prostaglandin structures of claims 1 and 5 are considered novel due to their incorporation of the piperidinyl-2-one ring system. The closest relevant prior art with respect to the instant structure can be found in Cameron et al., (US Patent Application 10/386307, pub date 11/6/03), wherein the prostaglandin analogs disclosed and claimed incorporate a pyrrolidin-2-one functionality and a thienyl linkage at position 4 of the structure as numbered in the instant specification on page 3. These structural differences are significant enough as to not anticipate the instant prostaglandin analog compounds claimed.

8. Claims 2, 3, 4, 6, 7, 8, and 10 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David E. Gallis whose telephone number is 571-272-9068. The examiner can normally be reached on Mon-Fri 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-1600. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



David E. Gallis
Patent Examiner